

REMARKS

I. THE REQUIREMENT FOR RESTRICTION

The Office Action requires restriction of the claims to one of the following inventions:

Group I, claims 1-56 and 58-63, drawn to compounds of formula II and III;

Group II, claim 57, drawn to a composition comprising at least one additional substance;

Group III, claims 64 and 75, drawn to a method of inhibiting the binding of p53 to a protein encoded by hdm2;

Group IV, claim 65, drawn to a method of treating a condition that results from the inhibition of one or more functions of a cellular protein that induces apoptosis, induces cell death or regulates the cell cycle by an HDM2 protein;

Group V, claims 66 and 67, drawn to a method of inducing apoptosis;

Group VI, claims 68-70, drawn to a method of treating cancer or a condition that results from the uncontrolled proliferation of cells;

Group VII, claim 71, drawn to a method of treating an inflammatory condition; and

Group VIII, claims 72-74, drawn to a method of treating an autoimmune disease or condition.

In response, Applicants confirm election of Group I, claims 1-56 and 58-63, with traverse. Applicants respectfully submit that, given that each of the claims in the present application regards specified 1,4-diazepine compounds, or use thereof, the search and examination of all of the claims in this application can be made without serious burden on the Office. Applicants therefore request that the Office examine claims 1-74 on the merits, even though they may include claims to independent or distinct inventions. Reconsideration and withdrawal of the requirement for restriction are respectfully requested.

II. THE REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

The Office Action rejects claims 1-55 and 58-63 under 35 U.S.C. § 112, second paragraph. In particular, the Office Action asserts that the terms "heteroaryl", "heterocyclic", "cycloalkyl" and "substituted" are indefinite. Applicants respectfully traverse the rejection

The present specification defines "heteroaryl" as:

The term "heteroaryl" as employed herein refers to groups having 5 to 14 ring atoms; 6, 10 or 14 pi electrons shared in a

cyclic array; and containing carbon atoms and 1, 2, 3, or 4 oxygen, nitrogen or sulfur heteroatoms (where examples of heteroaryl groups are: thienyl, benzo[b]thienyl, naphtho[2,3-b]thienyl, thianthrenyl, furyl, pyranal, isobenzofuranyl, benzoxazolyl, chromenyl, xanthenyl, phenoxathiinyl, 2H-pyrrolyl, pyrrolyl, imidazolyl, pyrazolyl, pyridyl, pyrazinyl, pyrimidinyl, pyridazinyl, indoliziny, isoindolyl, 3H-indolyl, indolyl, indazolyl, purinyl, 4H-quinoliziny, isoquinolyl, quinolyl, phthalazinyl, naphthyridinyl, quinazolinyl, cinnoliny, pteridinyl, 4aH-carbazolyl, carbazolyl, b-carbolinyl, phenanthridinyl, acridinyl, perimidinyl, phenanthrolinyl, phenazinyl, isothiazolyl, phenothiazinyl, isoxazolyl, furazanyl, phenoxazinyl, and tetrazolyl groups).

See page 28. The present specification defines the term "cycloalkyl" as follows:

The term "cycloalkyl" as employed herein by itself or as part of another group refers to cycloalkyl groups containing 3 to 9 carbon atoms. Typical examples are cyclopropyl, cyclobutyl, cyclopentyl, cyclohexyl, cycloheptyl, cyclooctyl and cyclononyl.

Id. The present specification defines "optionally substituted as follows:

The phrase "optionally-substituted" when not explicitly defined refers to a group or groups being optionally substituted with one or more substituents independently selected from the group consisting of hydroxy, nitro, trifluoromethyl, halogen, C1-6 alkyl, C1-6 haloalkyl, C1-6 alkoxy, C1-6 alkylendioxy, C1-6 aminoalkyl, C1-6 hydroxyalkyl, C2-4 alkenyl, C2-4 alkynyl, C6-10 aryl, phenoxy, benzyloxy, 5-10 membered heteroaryl, C1-6 aminoalkoxy, amino, mono(C1-4)alkylamino, di(C1-4)alkylamino, C2-6 alkylcarbonylamino, C2-6 alkoxycarbonylamino, C2-6 alkoxycarbonylalkyl, carboxy, C2-6 hydroxyalkoxy, (C1-6)alkoxy(C2-6)alkoxy, mono(C1-4)alkylamino(C2-6)alkoxy, di(C1-4)alkylamino(C2-6)alkoxy C2 10 mono(carboxyalkyl)amino, bis(C2 10 carboxyalkyl)amino, C2-6 carboxyalkoxy, C2-6 carboxyalkyl, carboxyalkylamino, guanidinoalkyl, hydroxyguanidinoalkyl, cyano, trifluoromethoxy, or perfluoroethoxy.

Preferred optional substituents include one or more substituents independently selected from the group consisting of nitro, hydroxy, carboxy, C1-4 alkoxy, C1-4 alkyl, halo, C1-4

haloalkyl, C1-4 alkylthio, thio, amino, mono(C1-4)alkylamino,
and di(C1-4)alkylamino.

See pages 29-30. One skilled in the art reading the claims in light of the definitions provided in the specification would readily understand the meaning of the terms "heteroaryl", "cycloalkyl" and "substituted". Further one skilled in the art would readily appreciate that a "heterocyclic" structure is a closed-ring structure in which one or more of the atoms on the ring is an element other than carbon. Reconsideration and withdrawal of the rejection of 1-55 and 58-63 under 35 U.S.C. § 112, second paragraph, are respectfully requested.

II. THE REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

The Office Action rejects claims 1-55 and 58-63 under 35 U.S.C. § 112, first paragraph. In particular, the Office Action asserts that the specification does not provide support for solvates or hydrates of the claimed compounds. In response, Applicants submit that the amendments to the claims obviate any basis for the rejection under 35 U.S.C. § 112, first paragraph. Reconsideration and withdrawal of the rejection of claims 1-55 and 58-63 under 35 U.S.C. § 112, first paragraph, are respectfully requested.

III. THE REQUEST FOR CO-PENDING APPLICATION TO WO04096134

Applicants respectfully submit that WO04096134 is the foreign counterpart to the present application. WO04096134 incorrectly cites U.S. Patent Application Serial No. 60/465,265 as its priority, wherein U.S. Patent Application Serial No. 60/465,264, the priority document for present Application Serial No. 10/829,040, is the correct Serial No.

IV. CONCLUSION

Early consideration and prompt allowance of the claims are respectfully requested. Should the Office require anything further, it is invited to contact Applicants' representative at the telephone number below.

Respectfully submitted,

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